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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,903	10/08/2004	Yasumichi Hitoshi	021044-003310US	1730

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EXAMINER

NATARAJAN, MEERA

ART UNIT PAPER NUMBER

1609

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/510,903

Applicant(s)

HITOSHI ET AL.

Examiner

Meera Natarajan

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claim 1-22, drawn to a method of identifying a compound that modulates cell cycle arrest and determining the chemical or phenotypic effect of the compound, classified in class 435, subclass 7.23.
- II. Claim 23, drawn to a method for identifying a compound that modulates cell cycle arrest and determining the physical effect of the compound prior to determining the chemical or phenotypic effect, classified in class 435, subclass 7.23.
- III. Claim 24-33, drawn to modulating cell cycle arrest in a subject by administering the compound identified by Group I, classified in class 435, subclass 7.23, class 514, subclass 12+, class 424, subclass 130.1+.
- IV. Claim 34, drawn to modulating cell cycle arrest by administering a target polypeptide, classified in class 514, subclass 12+.

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- V. Claim 35, drawn to modulating cell cycle arrest by administering a nucleic acid which encodes a target polypeptide, classified in class 514, subclass 44.
2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the methods of Groups I-V require the use of different products and require different steps. Each of the products in Groups I-V differ structurally and functionally and thus lack the same corresponding technical feature.
3. This application contains several claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The target polypeptide species are as follows:

- A. BRCA-1-Associated Protein-I (BAP-I)
- B. Nuclear Protein 95 (NP95)
- C. Fanconi anemia group A protein (FANCA)
- D. DEAD/H box polypeptide 9 (DDX9)
- E. insulin-like growth factor 1 receptor (IGFIR)
- F. ubiquitin-conjugating enzyme E2 variant 1 (UBE2V1)
- G. aldehyde dehydrogenase
- H. pyruvate kinase
- I. glucose-6-phosphate dehydrogenase

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J. HCDR-3

K. DEAD/H box polypeptide 21 (DDX21)

L. serine threonine kinase 15 (ARK2)

M. transmembrane 4 superfamily member 1

N. ERCC 1

The activity-measured species are as follows:

A. helicase activity

B. receptor tyrosine kinase activity

C. ubiquitination

D. ligase

E. ubiquitin hydrolase activity

F. ubiquitin ligase activity

G. receptor binding activity

H. receptor cross-linking activity

I. protease

J. endonuclease

The cancer cell species are as follows:

A. breast

B. prostate

C. colon

D. lung

The compound species are as follows:

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- A. antibody
- B. antisense molecule
- C. RNAi molecule
- D. small organic molecule
- E. circular peptide

Applicant is required, in reply to this action, to elect a single species of target polypeptide, activity measured, cancer cell, and compound to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner: Claims 1, 2, 10, 23, 34, and 35 involve multiple species; no claim is drawn to a single species. The following claim(s) are generic: Claim 1,2, 10, 23, 34, and 35.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: According to PCT

Rule 13.2 and to the guidelines in Section (f)(1)(B)(i) of Annex B of the PCT

Administrative instructions, all alternatives of a Markush Group must have a common structure, which is a significant structural element. Although the polypeptides listed in the claims share a common structure of a single amino acid, the compounds are not regarded as being of similar nature because the shared common structure is not a significant element. A common structure of a single amino acid is not a significant structural element because the amino acid is found in every peptide or protein. The group consisting of the different methods to measure activity differs in the method objectives, method steps and parameters and in the reagents used.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meera Natarajan Ph.D. whose telephone number is 571-⁰²³⁵272-7222. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN



MARY E. MOSHER, PH.D.
PRIMARY EXAMINER

1/4/07

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